



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9 6 8 6 '00 OCT 25 P2:21

Food and Drug Administration  
Washington, DC 20204

OCT - 2 2000

Daniel B. Mowrey, Ph.D.  
Basic Research, L.L.C.  
dba Silver Sage  
402 West 5050 North  
Provo, Utah 86404

Dear Dr. Mowrey:

This is in response to your letter of September 1, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Basic Research is making the following claims, among others, for the product "GlucoStart™":

"Blood Sugar Stabilizer;"

".... normalizing unstable blood sugar levels due to insalubrious calorie restricted diet."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely diabetes. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Denver, District Office, Office of Compliance, HFR-SW240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310

HFD-314 (Aronson)

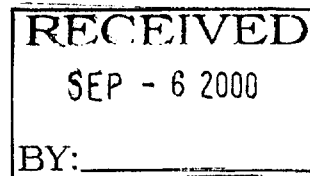
HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Nickerson, Barnett, Dorsey)

f/t:HFS-811:afp:9/27/00:72287:disc1

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**



This notification is being filed on behalf of Basic Research, L.L.C. dba Silver Sage that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 402 West 5050 North, Provo, Utah 84604. This notification is being made pursuant to section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **GlucoStart™**

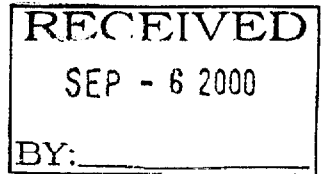
The text of each structure-function statement for which notification is now being given is:

- |                |   |
|----------------|---|
| (Statement 1): | "Blood Sugar Stabilizer."   |
| (Statement 2): | "An adjunct weight control compound."   |
| (Statement 3): | "Formulated to maximize your body's ability to burn fat by normalizing unstable blood sugar levels due to insalubrious calorie restricted dieting." |
| (Statement 4): | "Helps any primary weight loss program work better."  |
| (Statement 5): | "GlucoStart™ used alone is not a weight loss agent but augments the results obtained by primary weight loss products (like THERMOGENICS PLUS®)."    |

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

| <b>Statement<br/>Number</b> | <b>Identity of Dietary Ingredient(s) or Supplement(s)<br/>that is the Subject of the Statement:</b> |
|-----------------------------|---|
| 1                           | GlucoStart™   |
| 2                           | GlucoStart™   |
| 3                           | GlucoStart™   |
| 4                           | GlucoStart™   |
| 5                           | GlucoStart™   |

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The following identifies the brand name of each supplement for which a statement is made:

| <u>Statement Number</u> | <u>Brand Name</u>                      | <u>Label or Labeling?</u> |
|-------------------------|--|---------------------------|
| 1                       | Basic Research, L.L.C. dba Silver Sage | Both                      |
| 2                       | Basic Research, L.L.C. dba Silver Sage | Both                      |
| 3                       | Basic Research, L.L.C. dba Silver Sage | Both                      |
| 4                       | Basic Research, L.L.C. dba Silver Sage | Both                      |
| 5                       | Basic Research, L.L.C. dba Silver Sage | Both                      |

I, Daniel B. Mowrey, Ph.D., am authorized to certify this notification on behalf of Basic Research, L.L.C. dba Silver Sage. I certify that the information presented and contained in this Notification is complete and accurate, and that Basic Research, L.L.C. dba Silver Sage has substantiation that each structure-function statement is truthful and not misleading.

Dated this 1<sup>st</sup> day of September, 20 00

By:   
Daniel B. Mowrey, Ph.D.  
Consultant to Basic Research L.L.C.  
dba Silver Sage

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